

LBOIS
MB

RECEIVED

APR 19 1999

INVENTION DISCLOSURE FORM

LAW DEPARTMENT
MEDTRONIC, INC.

Please fill out this form as completely as possible. If the allotted space is not sufficient, use a separate sheet. Have your manager sign the form and forward it to the Patent Section of the Law Department. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney. For a copy of this form on diskette or for information on network retrieval of this form, please call Systems Support at x4111.

1. **Inventor(s) Full Name(s) Mail Stop** **Home Address (Include Zip Code)**
Todd Sheldon 38 East Pleasant Lake Rd.
Lee Stylos
Shannon Nelson
Rob Stadler

2. **Title of Invention:**
Ischemia detection utilizing electrical and mechanical means.

3. **How have others addressed this problem (List and attach any patents, books, articles, devices, Medtronic or competitor's products, or other background materials you used or which may be prior art)?**

Sorin Biomedica utilizes a lead tip accelerometer as a sensor for rate responsive pacing. They have published numerous articles and have some patents in this area.

Articles include:

PACE Vol. 19, Dec. 1996, An Implantable Intracardiac Accelerometer for Monitoring Myocardial Contractility.

4. **The invention is described on pages of Lab Notebook No. (Please attach copy).**
See section 9.

5. **When was a device built which included the invention? Simulation**
Who built it? Where is it? Todd Sheldon, Sheldon's office.
Who has supporting documents? Todd Sheldon
Who witnessed [REDACTED]

6. **Discuss the problems which the invention is designed to solve, referring to any prior devices of a similar nature with which you may be familiar.**

A significant percentage of Tachy and Brady patients have coronary artery disease. CAD is the number one cause of mortality in the developed world.

The invention is useful in increasing the specificity of detecting ischemia utilizing only electrical means.

The invention is useful in quantifying the degree of ischemic tissue involved by the degree of cardiac contractility drop as well as the degree of ST segment change.

The invention maybe useful in determining the location of the ischemic tissue.

7. State the advantages of the invention over presently known devices, systems or processes.

Ischemia detection utilizing only electrical means is often sensitive, but not very specific. The utilization of the accelerometer lead tip sensor in conjunction with electrical means of ischemia detection provides a method for differentiating significant ischemic events with changes in cardiac contractility from S-T segment changes without significant changes in cardiac contractility.

Also, the signals are independent and may therefore detect different areas of ischemia myocardium.

The relative relationship of multiple vectors may indicate the location of ischemic tissue.

The technology utilizes a bipolar lead. A competitive product requires a tripolar lead.

8. List all known and other possible uses for the invention.

Ischemia Detection

1. Ischemia diagnostics which relates the number and severity of ischemic events both in electrical ST segment terms and contractility terms. The diagnostic could guide the physicians decision for interventional therapy.
2. Early warning system during an acute myocardial infarction. Half of the people who have heart attacks wait two hours or longer before seeking treatment. Of those who survive, most damage to the heart occurs in the first hour.
3. As a detection system for a closed loop drug delivery. Possible drug candidates include long term beta blockers or thromolytic therapy. A parasympathic stimulation system has also been proposed as a method of treating ischemic events.

Accelerometer (Claim 1 has been demonstrated [REDACTED] Claims 2 and 3 [REDACTED])

1. The accelerometer can detect ventricular fibrillation and detects drops in contractility during ventricular tachycardia.
 2. The accelerometer can detect a ventricular contraction and be utilized for ventricular autocapture and is independent of the pacing electrode polarization which can be problematic in some lead models.
 3. The accelerometer can be useful in optimizing pacing timing parameters such as: the AV interval, the optimal multisite pacing site and timing, and the upper sensor and tracking rate.
 4. [REDACTED] utilizes the accelerometer sensor as a rate responsive sensor and have generally hypothesized its use in heart failure and tachyarrhythmia applications.
- 9. Specifically describe the invention and its operation. You may use and attach copies of sketches, prints, photographs and illustrations which should be signed, witnessed and dated. Use numbers and descriptive names in descriptions and drawings.**

The attached graph shows an example of ischemia initiated by occluding with an angioplasty balloon a canine coronary artery. The ischemia parameter which denotes the electrical means of detecting ischemia detects the occlusion. Also, there is a significant drop in the accelerometer measured contractility during the balloon occlusion. Also, note the large increase in the accelerometer measured contractility during dobutamine infusion.

10. List all features of the invention that are believed to be novel.

1. The use of the accelerometer lead tip signal (and the drop in the accelerometer signal during ischemia) as a confirmation of ischemia measured via electrical means.
2. The use of an accelerometer lead tip signal for further quantifying the extent of contractility drop during ischemia.
3. The use of an accelerometer lead tip signal (measuring contractility), accelerometer or activity signal (for measuring patient activity), and ST segment measurement via electrical means for ischemia detection. The signals will be utilized to detect/differentiate exercise or demand ischemia. Drops or plateaus in contractility during increasing or sustained exercise coupled with ST segment changes can be utilized to detect exercise ischemia.
4. The use of an accelerometer lead tip signal in detecting axis shift due to postural changes.
5. The use of the pre-ejection time interval (PEI) for determining whether the beat is to be evaluated for the ischemia algorithm.
6. The use of multi-axial accelerometers in a lead tip to add sensitivity to the ischemia detection via the accelerometer. The signals can be combined in OR fashion to increase sensitivity or combined in an AND fashion to increase specificity.
7. Additionally, changes in the magnitude and vector of multi-axial accelerometer can be fully utilized. Depending on the area of ischemia and location of the accelerometer lead tip, certain acceleration vectors may actually show an increase in contractility due to compensatory mechanisms within viable myocardium.
8. The use of the relative changes in orthogonal accelerometer signals to narrow the location of an myocardial infarction.
9. The accelerometer lead utilized requires a bipolar lead and senses unipolar. A competitive lead manufactured by SORIN utilized a tripolar lead and senses unipolar. The utilization of a bipolar lead versus tripolar lead is a significant competitive advantage and correlates with better reliability and smaller lead capsule length and diameter.
10. The accelerometer sensor utilized in the lead is built using MEMs technology. This technology allows a very high tolerance (i.e. possibly no lead calibration). Also, the extremely small size with strong sensing signal is ideal for the miniature environment on the lead tip.
11. The lead acceleration signal can be "tri-processed". The lead accelerometer signal in the following frequency ranges will measure the corresponding events:
 - a) 0-0.5 Hz measures the patient's/lead - posture/Orientation
 - b) 1-5 Hz measures the patient's activity
 - c) 5-100 Hz measures the patient's heart acceleration

11. Sale or Publication (Needed to establish the date of any printed publication, public use or sale, since no U.S. patent application may be filed after one year from such date.)

12. Inventor(s) Signature(s) (REQUIRED):

Todd J. Shultz
Signature

4/5/99
Date

Robert W. Stadler
Shawn J. Walsh

Manager's Comments

How is this invention important to your products, plans or goals?

Ischemia detection is a planned area of investigation for Brady Research. CAD is a large community overlapping all CAD patients. The use of a mechanical sensor along with electrical sensor for detection of ischemia holds promise for improved sensitivity and specificity.

Manager's Signature (REQUIRED)

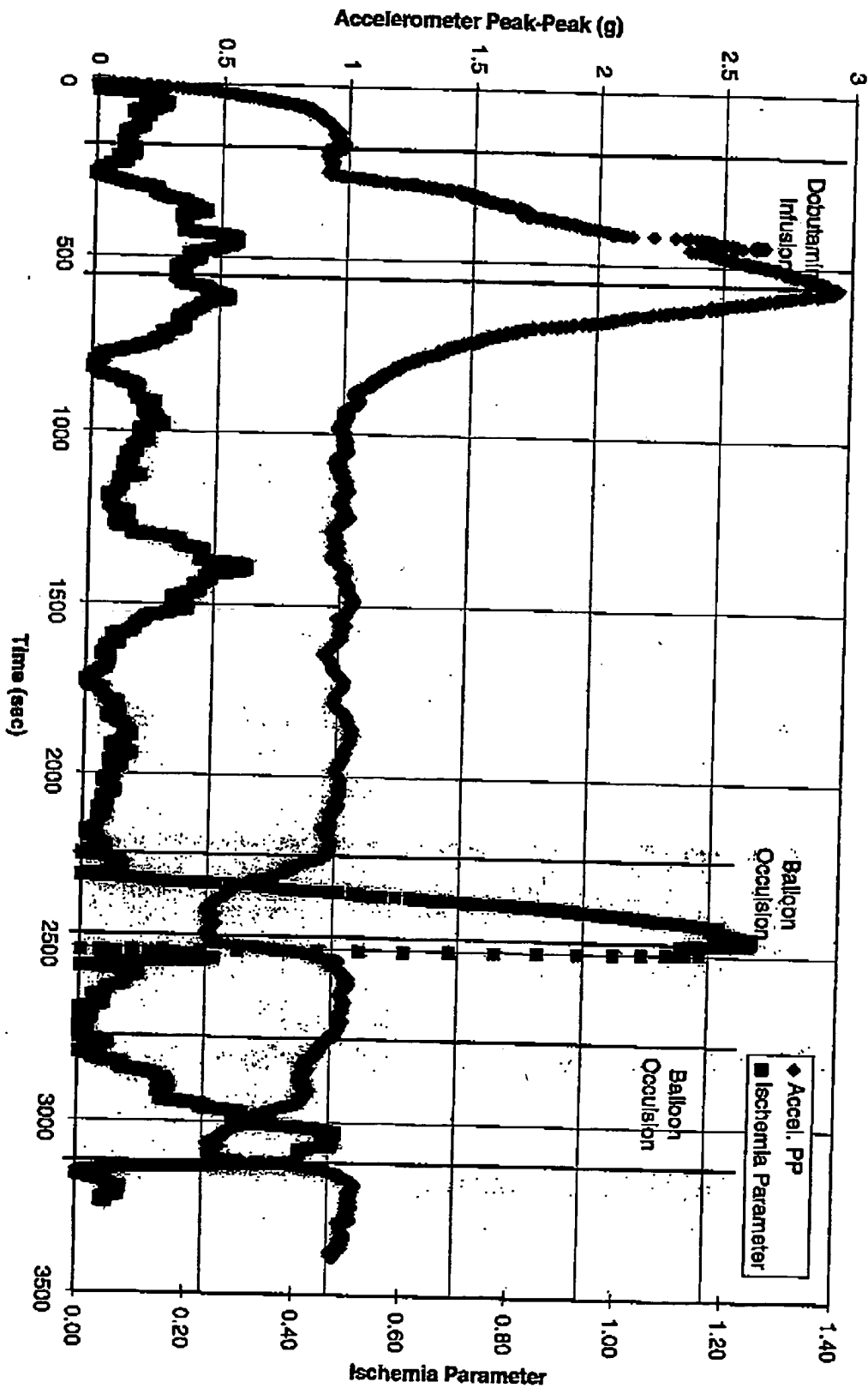
Date

4/15/98

(Manager: Please forward to Patent Section of Law Department upon completion of your review.)

casip

Acute Canine Test #6, Accelerometer and Ischemia Parameter.



P-8729.0
MBA
LB015**NEW FILE (INVENTION DISCLOSURE)**

CLERK

- X File to Hal Patton
- X Copy to Dave Thompson T284
(Promeon, Brady, Tachy, BRC, Vitatron, Micro-Rel,
Neuro, Synectics, CardioRhythm)
- Copy to Tom Armitage T210
(Valves-Mechanical)
- Copy to Jerry Hartlaub B132(LD068)

Heart Lecture Mgt.

— OUTSIDE INVENTOR

— ORIGINAL AGREEMENT ATTACHED

From: Kathy Illg
To: MSPEOS18.BRADY3.sheldt1, MSPEOS4.BRADY2.stylol1, M...
Date: 4/26/05 2:27pm
Subject: NEW FILE P8729.00 FROM MICHAEL B. ATLESS

WE HAVE SET UP A NEW FILE FOR YOUR INVENTION TITLED "ISCHEMIA DETECTION UTILIZING ELECTRICAL AND MECHANICAL MEANS". THE NEW FILE NUMBER IS P8729.00. PLEASE REFER TO THIS NUMBER WITH ALL FUTURE REFERENCES. THE FOLLOWING ATTACHMENT EXPLAINS THE PROCESS.